REMARKS

35 USC §102 and §103

The Examiner has rejected claims 1-4, 6-8, and 32 as being anticipated by US 6,290,985 to Ream et al (hereinafter "Ream"), stating that "Ream discloses a composition that comprises nictotine...guar gum hydrolysate....and isomalt". Examiner further asserts that "Ream discloses a composition that comprises ISOMALT and thus....this ISOMALT ought to have the ability to inherently form a glassy structure." Further, the Examiner has rejected claims 10-21 as being obvious in light of Ream by adding to the above remarks, in short, that while Ream does not disclose the amount of guar gum hydrosylate changes in amounts or concentrations will not support patentability without evidence indicating that amount is critical.

Applicants have amended independent claims 1 and 32 of the present application to more clearly point out and distinctly claim what Applicants believes is the invention. Specifically, Applicants have clarified the type of dosage form contemplated; an orally dissolving, hard boiled dosage form. Applicants have further clarified what is mean by the phrase "desired oral dissolution rate". Finally, in claim 1, Applicants have indicted that the active agent is substantially contained within the glass matrix. See specification, page 8, lines 4-5. No new matter has been added by virtue of these amendments. Additional amendments have been submitted to correct certain typographical errors present in the claim set. As amended, Applicants assert that Ream does not teach or disclose each and every element of the present claims and, thus, does not anticipate the present invention. Further, Applicants assert that Ream does not suggest or motivate one of skill in the art to modify the compositions taught therein to achieve the present invention.

The present invention, relates to a dosage form comprising a glassy matrix (or base) comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure, a water soluble gelling gum present in an amount which provides an oral dissolution rate of said glassy matrix such that a desired amount of said active agent is delivered via the oral mucosa prior to ingestion into the stomach, and an active agent, wherein the active agent is substantially contained within the glass matrix.

In contrast, the very focus of Ream is to provide a chewing gum which comprises a coating or shell that substantially encloses a tabletted gum center and wherein an active agent is present in the coating or shell. According to Ream, chewing of the entire gum formulation releases the active agent into the oral cavity and continued chewing of the gum creates pressure within the buccal cavity that forces the agent directly into the systemic system of the individual through the oral mucosa. There is no teaching in Ream of a dosage form which is in the form of a hard boiled glassy matrix, as this would not provide the "pressure within the oral cavity" that is taught by Ream. Moreover, while the gum center described in Ream may comprise a sugarless bulk sweetener such as ISOMALT, the active agent is present in the coating or shell of the gum only. Thus, it does not follow that there is present in Ream a glassy matrix base which substantially contains an active agent and the dissolution of which is controlled by the appropriate amount of a water soluble gelling gum present to achieve a desired dissolution rate. Further, there is no motivation to modify the formulation to achieve the dosage form of the present invention as Ream relates to a chewing gum, as described above, which is not orally dissolving and is not chewed and subsequently eaten, as the orally dissolving hard boiled dosage forms of the present invention may be.

Further, the Examiner has rejected claims 10-21 as being obvious in light of Ream, in short, asserting that the main difference in Ream versus the present invention is the failure to teach the level of guar gum hydrolysate that may be present in the compositions. Applicants assert that this improperly simplifies the differences between Ream and the present invention. As described above, the claims of the instant invention, differ from the Ream formulations in a number of ways. However, even if one could assume that the only difference between the instant formulations and the Ream formulations is an undisclosed level of guar gum hydrolysate, Applicants assert that one would still not be motivated to alter the Ream formulations to reach the present invention.

The Examiner implies the amount of water soluble gelling gum present in the instant invention is merely obtained through optimization of the Ream formula. However, Ream discloses only guar gum hydrolysate as being a suitable low caloric bulking agent for use in the compositions therein. Guar gum hydrolysate is a soluble, fermentable non-digestible saccharide that is generally used as a dietary

fiber. The properties of guar gum hydrolysate, differ from those of guar gum, in that hydrolyzed guar gum is much less viscous and is generally easier to incorporate into foodstuffs and the like. Thus, it would follow that direct substitution of guar gum for the guar gum hydrolysate, may not be appropriate as the physical properties of the chewing gum might be altered. Therefore, optimization of the levels of guar gum hydrolysate present in the Ream formulation would likely not result in the incorporation of a water soluble gelling gum, such as xanthan gum and the like, at the levels taught in the present invention.

Because there is no teaching or suggestion in Ream that the composition therein is an orally dissolving, hard boiled, dosage form comprising a glassy matrix base structure, which substantially contains the active agent therein, or that such composition comprises a water soluble gelling gum in an amount sufficient to provide an oral dissolution rate of the glassy base such that a desired amount of an active agent is delivered via the oral mucosa prior to ingestion into the stomach, Ream cannot be read to anticipate, nor render obvious, the present invention. Applicant respectfully requests withdrawal of both the §102 and §103 rejections based on the teachings of Ream.

35 USC §103

The Examiner further rejects claims 1-32 under 35 USC §103 (a) as being obvious in light of Ventouras (US 6,183,775 B1) in view of Rapp et al. (US 6,180,143 B1, hereinafter "Rapp") or Burnick et al. (US2003/0017202 A1, hereinafter "Burnick"). Further, the Examiner rejects claims 10-21 in light of Ream. Applicant maintains that Ventouras, taken alone or in combination with either Rapp or Burnick does not render claims 1-32 obvious.

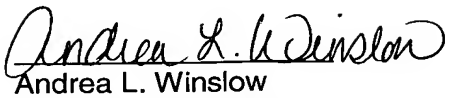
Ventouras relates to a controlled release direct compression lozenge comprising an insoluble matrix for delivery of an active substance. Ventouras requires three essential components, a soluble filler, an insoluble film forming agent, and a swellable polymer. Ventouras does not teach a dosage from comprising a glassy matrix where the active agent is substantially contained therein. Ventouras does not teach the incorporation of a sugar alcohol even capable of forming a glassy matrix.

The Examiner relies on Rapp and Burnick for the principle that sweetening agents, such as ISOMALT, are known for use in nicotine formulations. Rapp relates to chewing gum compositions which may comprise 1,1-GPS alone or in combination with other sweeteners. Such sweeteners are incorporated into the Rapp compositions to increase flexibility of the gum and prevent drying out of the gum during storage. Burnick relates to an oral dosage form comprising a soft core encased within a brittle shell coating that also my include sweeteners of the type described above. In response, Applicant maintains that modification of Ventouras merely to include a sugar alcohol capable of forming a glassy matrix, such as ISOMALT, does not inherently produce a glassy matrix which substantially contains an active agent therein. Such a glassy matrix is present in the hard boiled dosage forms of the present invention, however, such a matrix would *not* result by merely incorporating a sugar alcohol capable of forming a glassy matrix into a directly compressed lozenge.

Clearly, neither Rapp nor Burnick relates to an oral dosage form comprising a glassy matrix of a non-hygroscopic sugar alcohol which substantially contains an active agent therein, as a glassy matrix would not provide an acceptable chewing gum or chewable soft core composition. Thus the combination of either of these references with Ventouras would not result in the compositions of the present invention, in particular, an orally dissolving, hard boiled, dosage form comprising a glassy matrix base structure, which substantially contains the active agent therein, or that such composition comprises a water soluble gelling gum in an amount sufficient to provide an oral dissolution rate of the glassy base such that a desired amount of an active agent is delivered via the oral mucosa prior to ingestion into the stomach.

Applicant respectfully requests that the Examiner's rejections based on 35 USC §103(a) in light of Ventouras in combination with Rapp or Burnick, be withdrawn.

Respectfully submitted,



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